

**d.) Remarks.**

Applicant has canceled claim 68, amended claims 58, 60, 62 and 63, and added new claims 69-95. No new matter or new issues are introduced with these amendments and new claims. Thus, claims 1-26, 40-58, 60-63, and 69-95 are currently pending.

**Remarks Regarding Objection**

Claim 63 stands objected to for being dependent on a withdrawn claim. Claim 63 has been amended and this objection is moot.

**Remarks Regarding 35 U.S.C. § 112, First Paragraph**

A. Claims 58, 60, 62, 63 and 68 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly not adequately described. Applicant respectfully traverses this rejection.

Specifically, it is alleged in the Office Action that applicant has not adequately described the term inhibin and cites to a Federal Circuit opinion, *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, which allegedly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” Applicant respectfully notes that the examiner has misapplied this case. The claimed invention is a method, which is both fully and completely described to one of ordinary skill in the art. The invention, as the examiner has misunderstood, is not the inhibin protein. In fact, inhibin protein, as well as subunits and regions thereof, is well known to those of ordinary skill in the art. Applicant specifically refers the examiner to any one of the references cited in this case for further clarification.

Thus, the rejection of claims 58, 60, 62, 63 and 68, under 35 U.S.C. § 112, first paragraph, is in error, and applicant respectfully requests that it be withdrawn.

B. Claims 58, 60, 62, 63 and 68 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly not adequately enabled. Applicant respectfully traverses this rejection.

Specifically, it is alleged in the Office Action that applicant has not demonstrated that the claimed invention operates as claimed. Applicant respectfully disagrees.

However, in an effort to expedite prosecution, the claims have been amended to recite that the claimed methods are directed to screening for a down-regulation of inhibin. Enablement for down regulation of inhibin levels is indicated throughout the application such as, for example, Example 14, and Figure 8 (see, specification page 43, lines 9-10, 14-15, and 17).

Thus, the rejection of claims 58, 60, 62, 63 and 68, under 35 U.S.C. § 112, first paragraph, is moot, and applicant respectfully requests that it be withdrawn.

**Remarks Regarding 35 U.S.C. § 102(b)**

Claims 58, 60, 62 and 63 stand rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by Teni et al. ("Teni"). Applicant respectfully traverses this rejection.

In the Office Action, it is alleged that Teni discloses measuring the level of a prostatic inhibin-like peptide ("PIP") and that the examiner has concluded that PIP is encompassed within the meaning of inhibin in the claims. Further, the examiner specifically identifies applicant's prior statements that PIP and inhibin are different proteins, but alleges that no proof was provided.

In applicant's Amendment filed and dated September 26, 2002, applicant indicated that PIP was not an inhibin protein and cited to an abstract of an article by Gorden et al. (Biology of Reproduction 36:829-35, 1987; "Gordon"), which indicates that Beta-microseminoprotein (i.e.  $\beta$ -MSP) is not an inhibin (*see* Title).

Now, although absolute proof is not believed to be required here, enclosed herewith is a copy of NCBI Database Reference P08118, which details eight accepted names for PIP protein including both PIP and  $\beta$ -MSP. Thus, PIP and  $\beta$ -MSP are one and the same proteins.

Thus, as was previously noted to the examiner, as indicated in Gordon, the protein identified as  $\beta$ -MSP is not believed to be an inhibin because  $\beta$ -MSP and tryptic peptides of  $\beta$ -MSP failed to depress follicle-stimulating hormone ("FSH") levels in the medium at any of the doses tested (10-10,000 ng/ml). However, under the same conditions, partially purified inhibin from porcine follicular fluid ("pFFI") showed a dose-dependent inhibition of FSH secretion with a 50% inhibitory dose at 50 ng, which paralleled that seen with standard inhibin (*see* Gordon abstract, discussion, and Figure 4).

Applicant respectfully asserts that PIP and  $\beta$ -MSP are in fact the same protein and that  $\beta$ -MSP is not an inhibin protein of the claimed invention. Accordingly Teni does not disclose or suggest the claimed invention.

In addition, enclosed herein is a BLAST 2 Sequence alignment of the sequences of PIP and inhibin. As indicated, no significant similarity was found again demonstrating that the proteins are different.

Thus, for at least these reasons, the rejection of claims 58, 60 and 62, under 35 U.S.C. § 102(b), is overcome as moot, and applicant respectfully requests that it be withdrawn.

#### **Remarks Regarding New Claims**

Applicant has added new claims 69-95. All of these new claims are fully supported in the specification. Further, most of the new claims are dependent from independent claim 58 and the remaining claims are dependent from claims 83 or 95. Neither of the two new independent claims contain new issues that would require an additional search and, thus, no new matter or new issues are presented herein. The claims are simply added to further define the scope of the invention.

## Conclusion

The application is believed to be in condition for allowance and the prompt issuance of a Notice of Allowance is respectfully requested. In addition, if the application is considered to be in condition for allowance, applicant respectfully request that the species restriction imposed in the Office Action, mail dated March 9, 2001, be withdrawn and that claim 61, the one claim that was subject to the species restriction, be included in the application and amended in accordance with similar amendments made to claim 62 herein.

If there are any fees due with the filing of this Response, including any further fees for an extension of time, applicant respectfully requests that extension and requests that any and all such fees be charged to the undersigned's Deposit Account No. 03-1952, referencing Attorney Docket No. 229752000800.

Respectfully submitted,  
Morrison & Foerster LLP

Dated: September 30, 2004

By: 

James Remenick  
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Enclosed: NCBI Database Reference P08118  
BLAST 2 Sequence alignment

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BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.9 [May-01-2004]

Sequence 1	lcl seq_1	Length 366	Locus PO8118
Sequence 2	lcl seq_2	Length 114	Locus AAH06391

*No significant similarity was found*

**LOCUS** P08118 114 aa linear PRI 15-JUN-2004

**DEFINITION** Beta-microseminoprotein precursor (Prostate secreted seminal plasma protein) (Prostate secretory protein PSP94) (PSP-94) (Seminal plasma beta-inhibin) (Immunoglobulin binding factor) (IGBF) (PN44).

**ACCESSION** P08118

**KEYWORDS** Signal; Polymorphism; Alternative splicing; Direct protein sequencing.

**SOURCE** Homo sapiens (human)

**ORGANISM** Homo sapiens

1 mnvllgsvvi fatfvtlena scyflpncgv pgdstrkcmd lkgnkhpins ewqtdncetc

61 tcyeteiscc tlstvpgyd kdncqrifkk edckyivvek kdpkktcsvs ewii

**LOCUS** AAH06391 366 aa linear PRI 29-JUN-2004

**DEFINITION** Inhibin alpha subunit, precursor [Homo sapiens].

**ACCESSION** AAH06391

**VERSION** AAH06391.1 GI:13623557

**DBSOURCE** accession BC006391.2

**KEYWORDS** MGC.

**SOURCE** Homo sapiens (human)

**ORGANISM** Homo sapiens

Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;

Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.

**ORIGIN**

1 mvlhlflfl ltpqgghscq glclarelvl akvralfida lgppavtreg gdpgvrrlpr

61 rhalggfthr gsepeeedv sqailfpdtd ascedksaar glaqeaeegl frymfrpsqh

121 trsrqvtsaq lwfhtglrdq gtaasnssep llglalspg gpvavpmslg happhwavlh

181 latsalsilt hpvlvllrc plctcsarpe atpflvahtr trppsggera rrstplmswp

241 wpsalrllq rppeepaaha nchrvalnis fqelgwerwi vyppsifthy chggcgllhip

301 pnslpvpga pptpaqpysl lpgaqpccaa lpgtmrplhv rttsggysf kyetvpnllt

361 qhcaci